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EXAMINER	
SNYDER, STUART	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,448	DREVET ET AL.	
	Examiner	Art Unit	
	STUART W. SNYDER	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-53,55-57 and 67-79* is/are pending in the application.

4a) Of the above claim(s) *79* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35,36,39,44 and 54-57* is/are rejected.

7)☒ Claim(s) *40-47, 49-53, and 67-78* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/209*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 35-53, 55-57, and 67-79 are pending. Amendment of claims 35-53 and 55-57; cancellation of claims 54 and 58; and addition of new claims 67-79 in Applicants filing of 8/10/2009 is acknowledged.

Election/Restrictions

2. Newly submitted claim 79 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claim is drawn to an oligonucleotide that encodes an HIV immunogenic composition comprising a tat protein, fragment thereof, or artificial variant thereof. It has a different and distinct chemical nature from the claimed tat protein, fragment thereof, or artificial variant thereof.

   Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 79 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112, 1st ¶

3. Rejection of claims 35-58 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **withdrawn** in view of amendment of the claims.

Claim Rejections - 35 USC § 112, 2nd ¶

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Rejection of claims 36, 44, 45, 46, 49, 50, 53, 54, and 58 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of amendment of the claims..

5. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 39 recites "said non-metal ligand in a) or in c) is the HIV vpr protein". The word ligand normally is defined as "a molecule or group which binds to another molecule (usu. a macromolecule) with a high degree of specificity (OED online edition, 1989). It is not known in the virological arts that HIV vpr protein binds with specificity to HIV tat, nor has Applicant demonstrated such association. Because of this, vpr can not be considered a ligand. Thus, the claim is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Rejection of claims 35, 36, 44 and 54 under 35 U.S.C. 102(b) as being anticipated by Marasco, et al. is **withdrawn** in view of amendment of the claims and Applicants' arguments.

7. Claims 35-37, 42, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Hakansson and Caffrey (Structural and Dynamic Properties of the HIV-1 Tat Transduction Domain in the Free and Heparin-Bound States. Biochemistry 2003, 42, 8999-9006). The claims are drawn to an immunogenic composition comprising an isolated tat antigen complexed with a ligand comprising, *inter alia*, heparin; claim 38 requires heparin have a MW of 6000 or 15000 Da and claim 48 requires the tat antigen be monomeric.

Hakansson and Caffrey teach a composition comprising an 11 amino acid domain of tat complexed with a 6000 Da MW heparin molecule (see the first paragraph of the Materials and Methods section spanning pages 8999 and 9000). Furthermore, it is well known in the immunological arts that heparin per se is immunogenic and antibodies produced against it may cause problems for those undergoing certain cardiologic therapies precisely because these patients produce antibodies against the anti-clotting agent heparin (see, for example, http://www.sciencedaily.com/releases/2005/12/051203122633.htm). Furthermore, according to Hakansson and Caffrey, the 11 amino acid tat moiety of the so-called PG-TTD fusion protein is expected to be in an extended form and at least partially exposed so as to remain immunogenic. Accordingly, both the tat

fragment and heparin ligand retain immunogenicity in complex. Thus, Hakansson and Caffrey teach each and every limitation of claims 35-37, 42 and 48.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hakansson and Caffrey as applied to claims 35-37, 42 and 48, in further view of Lindblad (Lindblad, E.B. Aluminum compounds for use in vaccines. Immunology and Cell Biology (2004) 82:497–505). Claims 55-57 add the limitation that the vaccine composition of either claims 35 or 55 further comprise an adjuvant (claim 55), especially aluminum hydroxide (claim 57) and/or pharmaceutically acceptable vehicle and/or a carrier substance.

Linblad reviews the history of aluminum based compounds and restates the common and long held knowledge that vaccines often comprise aluminum-based adjuvants because of the long safety history and profile. Furthermore, the USDA and FDA approved vaccines listed in Linblad (see page 3662, table 1) each are formulated in pharmaceutically acceptable vehicles, especially sterile, pyrogen free water or PBS. Thus, Linblad, *et al.* teaches each and every limitation of claims 55-57 not taught by Hakansson and Caffrey

It would have been obvious to combine the teachings of Hakansson and Caffrey and Linblad to arrive at the instantly claimed invention of claims 55-57. A skilled artisan would have been motivated to include aluminum-based adjuvant and pharmaceutically and pharmaceutically acceptable carriers in the composition of Hakansson and Caffrey because of the desire to increase the immune response of the immunogen, the long safety record of aluminum-based adjuvants and, in the case of pharmaceutically acceptable carrier, the desire to safely administer the vaccine explicitly and implicitly taught by Linblad. Furthermore, a skilled artisan would have a reasonable expectation of success in combining the two compositions because of the effectiveness of aluminum-based adjuvants in increasing the immunogenicity of a wide variety of immunogens (see Linblad, page 3662, table 1). Thus, it would be *prima facie* obvious to formulate a stabilized tat composition with an aluminum-based adjuvant in a pharmaceutically acceptable carrier as required by the limitations of claims 55-57.

Allowable Subject Matter

9. Claims 40-47, 49-53, and 67-78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on (571) 272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

Stuart W Snyder
Examiner
Art Unit 1648

sws